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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/833,637 04/13/01 KODAMA

Y 011900-309

PLATON N. MANDROS

HM22/1022

EXAMINER

BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. BOX 1404
ALEXANDRIA VA 22313-1404

KAM, C

ART UNIT

PAPER NUMBER

1653

DATE MAILED:

10/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/833,637 | KODAMA ET AL. |
| | Examiner | Art Unit |
| | Chih-Min Kam | 1653 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.
 - 4a) Of the above claim(s) 12-15 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-11 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant is required to provide the English translation of the foreign application (Application Japan 2000-113913) since Applicant claims for foreign priority under 35 U.S.C. 119(a)-(d).

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:
 - I. Claims 1-11, drawn to a glycoprotein which specifically binds to urease of *Helicobacter pylori*, or, an inhibitor of *Helicobacter pylori* colonization, a pharmaceutical composition or a food comprising the glycoprotein, classified in class 514, subclass 8.
 - II. Claims 12 and 13, drawn to a method of inhibiting *Helicobacter pylori* colonization in mammals comprising orally administering a glycoprotein, classified in class 514, subclass 8.
 - III. Claims 14 and 15, drawn to a method for preventing or treating a disease associated with *Helicobacter pylori* in mammals comprising orally administering a glycoprotein, classified in class 514, subclass 8.
2. The inventions are distinct, each from the other because of the following reasons:
The product of Invention I and the methods of Invention II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

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process of using that product (MPEP § 806.05(h)). In the instant case the methods of Inventions II and III are alternative processes of use of the product of Invention I.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, and because Inventions I-III require different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

During a telephone conversation with Susan Dadio on October 12, 2001 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-11. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-15 were withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Objections

3. Claims 1-11 are objected to because of the use of the term “glycoprotien” or “albumen”. Appropriate correction is required.
 4. Claims 1-11 are objected to because of the use of the term “Helicobacter pylori”.
- Bracketing or underlining are commonly used to indicate amendments or changes in the claims

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as provided in 37 CFR 1.121(a)(2)(ii) and are normally not intended to be printed in the published patent. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim is drawn to a glycoprotein. As written, the claim reads on a product of nature as for example set forth at page 2, lines 13 of the instant specification and should be amended to indicate the hand of the inventor, for example, by insertion of “isolated or purified” in connection with glycoprotein to identify a product that is not found in nature.—See MPEP § 2105.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1 and 4 -6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, as directed to “...which specifically binds...” is unclear as to the definition of specifically for degree of affinity or of binding. The tests at pages 17 and 18 do not define specific nor non-specific nor what the bounds are for the term in the claim. Claims 4-6 are indefinite because of the use of the term “derived from”. The term “derived from” renders the

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claim indefinite, it is unclear how different is the substance obtained from whey of bovine milk or the albumin of chicken eggs as compared to the original substance in bovine milk or chicken eggs.

7. Claims 8-9 are indefinite because of the use of the term “and/or”. The term “and/or” renders the claim indefinite, it is unclear which process is included, e.g., is “preventing”, “treating” or both are included.

8. Claims 8-9 and 11 are indefinite because of the use of the term “a disease”. The term “a disease” renders the claim indefinite, it is unclear which disease is treated by the pharmaceutical composition.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. Claims 1-11 are rejected under 35 U.S.C. 102(e) as anticipated by Kodama *et al.* (US Patent 6,235,709).

Kodama *et al.* disclose an inhibitor of *Helicobacter pylori* (Hp) colonization comprises an active ingredient mucin which contains a high molecular weight glycoprotein (column 3, line 62-column 4, line 11, column 3, lines 28-31). The mucin (glycoprotein) can inhibit the adhesion of urease of Hp to gastric mucosa in the stomach by binding the urease (column 5, lines 26-40), which meets the criteria of claims 1-3 and 7. The mucin can be obtained from whey of bovine

milk or from albumin of chicken eggs (column 4, line 16-column 5, line 25, Examples 1 and 2), which meets the criteria of claims 4-6. The mucin can be used as inhibitor of Hp colonization in the stomach and is useful for preventing or treating diseases caused by or associated with Hp such as peptic ulcers (column 3 lines 31-34; column 5, lines 36-41). The inhibitor of Hp colonization comprising mucin may be formulated with a pharmaceutical acceptable carrier to form a pharmaceutical composition and may be used along with an inhibitor of gastric acid secretion, which is more effective in eliminating Hp from the stomach than mucin alone (column 5, line 48-column 6, line 9), this meets the criteria of claims 8, 10 and 11. The mucin which is the inhibitor of Hp colonization can be formulated into food for its anti Hp activity (column 3, lines 41-47; column 5, lines 42-46; column 6, lines 10-30), which meets the criteria of claim 9.

Note that the process steps are given no weight in claim 1 because the process steps do not materially change the glycoprotein and the patentability is based on the product per se.

Conclusion

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

October 17, 2001

Chris Low S-2-h
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600